510(k) Summary
As required by 21CFR 807.92(c)

510(k) Number: K132655

Date Prepared: August 23, 2013

NOV 2 0 2013

Submitter Information:

Submitter's Name/
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Device Information:

Trade Name/Proprietary Name: RetroArc™ Retropubic Sling System
Common Name: Surgical Mesh
Classification Registration: 21 CFR § 878.3300
Product Code: OTN

Predicate Device:

SPARC® Sling System (K081613)

Device Description:

The RetroArc System is a sterile, single use system, consisting of one plastic handle, two stainless steel delivery needles and a sling assembly. The tip portion of each delivery needle is configured to allow for passage through tissue. The opposite end of the needle is configured to connect with the plastic handle. The handle is detachable and is used to direct both delivery needles through tissue. The sling assembly includes one piece of loosely knitted polypropylene mesh with an integrated adjustment suture, two removable plastic insertion sheaths, and two connectors attached to the insertion sheaths. The adjustment suture is an integral feature woven into the

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mesh which limits the overall stretch of the mesh arms during the procedure. The integrated suture and mesh, allow for adjustment of the sling after initial placement in the patient without the use of additional tools. The two plastic sheaths overlap during placement and allow for convenient travel of the sling through the tissue. The connectors, sheaths, and delivery instruments are used to facilitate placement of the mesh assembly, and are not implanted. The mesh component is not absorbed by the action of tissue in-growth or tissue enzymes

Indications for Use:

The RetroArc Retropubic Sling System is intended for the placement of a suburethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Comparison to the Predicate Device:

The fundamental scientific technology on the RetroArc™ Retropubic Sling System is unchanged from the predicate device. The intended use and indication for use is identical to that of the predicate device. In addition, the RetroArc System utilizes the same sling assembly, utilizing the identical implant materials and design principles as the predicate SPARC Sling System (K081613). The primary change to the device is the delivery instruments to allow for placement of the sling using a retropubic approach. The changes to the delivery needle include a longer length, an increased needle angle, and larger needle diameter. The plastic handle was also modified to allow for detachment of the delivery needle after placement. This allows one handle to be used to direct both delivery needles through tissue.

Summary of Non-Clinical Testing:

Bench testing was performed to support this submission. Results of the testing demonstrate that the RetroArc Retropubic Sling System meets product specification and performance requirements.

The following testing has been successfully completed:

- Sterilization
- Shelf Life
- Biocompatibility
- Performance Testing (Bench)
    - Delivery Instrument Torsional Strength

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- Needle Connection Cycling
- Needle Connection Push Force
- Needle Disconnection Pull Force
- Needle Disconnection Button Force

- Performance Testing (Cadaver)
  - Physician Questionnaire
  - Cadaver Evaluation
  - Cadaver Dissection

Clinical Testing:

No clinical testing was performed to support this Traditional 510(k) Premarket Application.

Statement of Equivalence:

The RetroArc Retropubic Sling System has the identical indications for use and fundamental scientific technology as the predicate device. Based on this and the design and engineering data provided in the pre-market notification, the RetroArc Retropubic Sling System has been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2013

American Medical Systems, Inc.
Renee Mellum
Sr. Regulatory Affairs Specialist
10700 Bren Road West
Minnetonka, MN 55343

Re: K132655
Trade/Device Name: RetroArc™ Retropubic Sling System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: August 23, 2013
Received: August 26, 2013

Dear Renee Mellum,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132655

Device Name: RetroArc™ Retropubic Sling System

Indications for Use:

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Prescription Use __X____ (Per 21 CFR 801 Subpart D) AND/OR Over-The Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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